

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference R9138WO	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/FR2004/001962	International filing date (day/month/year) 22.07.2004	Priority date (day/month/year) 31.07.2003
International Patent Classification (IPC) or national classification and IPC A61K31/132, A23L1/305, A61P25/00, A61P31/12, A61 P9/10		
Applicant UNIVERSITE DE RENNES 1		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>8</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																									
<p>4. This report contains indications relating to the following items:</p> <table><tr><td><input checked="" type="checkbox"/></td><td>Box No. I</td><td>Basis of the report</td></tr><tr><td><input type="checkbox"/></td><td>Box No. II</td><td>Priority</td></tr><tr><td><input checked="" type="checkbox"/></td><td>Box No. III</td><td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td></tr><tr><td><input type="checkbox"/></td><td>Box No. IV</td><td>Lack of unity of invention</td></tr><tr><td><input checked="" type="checkbox"/></td><td>Box No. V</td><td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td></tr><tr><td><input type="checkbox"/></td><td>Box No. VI</td><td>Certain documents cited</td></tr><tr><td><input type="checkbox"/></td><td>Box No. VII</td><td>Certain defects in the international application</td></tr><tr><td><input type="checkbox"/></td><td>Box No. VIII</td><td>Certain observations on the international application</td></tr></table>		<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand	Date of completion of this report																								
Name and mailing address of the IPEA/EP	Authorized officer																								
Facsimile No.	Telephone No.																								

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/FR2004/001962

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:

- ☐ international search (Rule 12.3 and 23.1(b))
☐ publication of the international application (Rule 12.4)
☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☒ the description:

pages 1-18 as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ the claims:

nos. 1-31 as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* _____ received by this Authority on _____

nos.* _____ received by this Authority on _____

☒ the drawings:

sheets 1/4-4/4 as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/FR2004/001962

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application
- ☒ claims Nos. 1-15; 21, 22, 30, 31 (in part)

because:

- ☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. 1-15; 21, 22, 30, 31 (in part)

- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐

has not been furnished

☐

does not comply with the standard

the computer readable form

☐

has not been furnished

☐

does not comply with the standard

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

- ☒ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/FR2004/001962

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims		YES
	Claims	16-31	NO
Inventive step (IS)	Claims		YES
	Claims	16-31	NO
Industrial applicability (IA)	Claims	16-31	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

1. Cited documents

Reference is made to the following documents:

D1: KERGOZIEN S ET AL: "Polyamine deprivation provokes an antalgic effect" LIFE SCIENCES, vol. 58. no. 24, 1996, pages 2209-2215, XP002309789;

D2: US-A-6 114 392 (GILAD GAD M ET AL)
5 September 2000 (2000-09-05);

D3: EP-A-1 085 011 (ORIDIGM CORP) 21 March 2001
(2001-03-21);

D4: WO 03/051348 A (MURPHY MICHAEL A) 26 June 2003
(2003-06-26);

D5: GILAD G M ET AL: "EARLY POLYAMINE TREATMENT ENHANCES SURVIVAL OF SYMPATHETIC NEURONS AFTER POSTNATAL AXONAL INJURY OR IMMUNOSYMPATHECTOMY" DEVELOPMENTAL BRAIN RESEARCH, vol. 38, no. 2, 1988, pages 175-181, XP002271146 & ISSN: 0165-3806;

D6: GILAD G M ET AL: "TREATMENT WITH POLYAMINES CAN PREVENT MONOSODIUM GLUTAMATE NEUROTOXICITY IN THE RAT RETINA" LIFE SCIENCES, vol. 44, no.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/FR2004/001962

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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25, 1989, pages 1963-1969, XP002271147 & ISSN: 0024-3205;

D7: GILAD G M ET AL: "Novel polyamine derivatives as neuroprotective agents." THE JOURNAL OF PHARMACOLOGY ET EXPERIMENTAL THERAPEUTICS. OCT 1999, vol. 291, no. 1, October 1999 (1999-10), pages 39-43, XP002271148 ISSN: 0022-3565;

D8: WO 95/00041 A (UNIV RENNES ; MOULINOX JACQUES PHILIPPE (FR); QUEMENER VERONIQUE (FR))
5 January 1995 (1995-01-05);

D9: WO 95/00042 A (UNIV RENNES; MOULINOX JACQUES PHILIPPE (FR); QUEMENER VERONIQUE (FR))
5 January 1995 (1995-01-05).

2. Prior art disclosures

2.a Document D1 describes how polyamine deprivation reduces the pain threshold in mice. The tests used to demonstrate this are the same as the ones in the application.

2.b Document D2 describes the use of orally delivered polyamines in the treatment of Alzheimer's and Parkinson's disease and other neurodegenerative diseases.

2.c Document D3 describes the use of polyamines, in particular, spermidine and putrescine derivatives, in the treatment of Alzheimer's disease, depression and psychoses.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/FR2004/001962

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
2.d	Document D4 describes the use of polyamine derivatives in the treatment of neurodegenerative diseases.
2.e	Document D5 discloses that treatment with putrescine, spermidine and spermine reduces neuron loss in axotomised mice.
2.f	Document D6 discloses that the use of polyamines can have a general effect on neuron survival.
2.g	Document D7 discloses that novel polyamines have a neuroprotective effect.
2.h	Document D8 describes the pharmaceutical use of food compositions that contain less than 1,600 picomoles/g of polyamine. Said compositions are described in detail.
2.i	Document D9 describes the pharmaceutical use of food compositions that contain less than 1,600 picomoles/g of polyamine. Said compositions are described in detail.
3.	<p>Novelty - PCT Article 33(2)</p> <p>The subject matter of claims 16-31 (in part) does not fulfil the requirement of novelty defined in PCT Article 33(2).</p> <p>The subject matter of said claims is anticipated by document D1, the disclosure of which is</p>

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/FR2004/001962

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

described above.

4. Inventive step - PCT Article 33(3)

Since the presence of an inventive step can only be established if the claims are novel, it has not been possible to determine whether the present application fulfils the requirements set forth in PCT Article 33(1). The applicant's attention is, however, drawn to the fact that the application as filed contains only tests that demonstrate the activity of the compositions in pain treatment. Since there are no tests relating to the other uses, it has not been possible to evaluate the presence of an inventive step because it is impossible to verify whether the corresponding technical problem has been effectively solved. What is more, cited prior art documents D2-D9 demonstrate that polyamines are, in fact, curative agents for neurodegenerative diseases. As a result, it is unlikely that a foodstuff having a low polyamine content, as claimed, could treat the same diseases.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box III:

1. Claims 1-15 (in full) and 21, 22, 30 and 31 (in so far as they refer to claims 1-15) are so unclear that **they could not be searched**. Said claims do not provide a positive definition of the subject matter for which protection is sought because they indicate only what the compositions must not contain. **As a result, it has not been possible to compare said subject matter with the prior art or to search the databases (which, in particular, describe material compositions in terms of what they contain, not what they do not contain).**
2. Notwithstanding these considerations, the present application as filed discloses only the use of the claimed compositions as analgesics (PCT Article 5). None of the other claimed uses is supported by the tests described in PCT Article 6.

In view of these objections, the examination has been limited to subject matter that was searched and is clear, supported and sufficiently disclosed, namely the use of the compositions as per claims 16-20 and 23-29 (in full) and 21, 22, 30 and 31 (in so far as they refer to claims 16-20) in the treatment of pain.